

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. In the claims

As shown in the foregoing LIST OF CURRENT CLAIMS, the claims have been amended to more clearly point out the subject matter for which protection is sought.

Claims 1-18 remain canceled.

Claim 19 is amended to clarify that the fine thread is used in two manners, the first is if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, the second is if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread. It is respectfully submitted that no new matter is added, since support for the amendments may be found, for example, at least in Figs. 27 through 30, 32, 33, 36, and 37 of the pending application and, for example, at least on page 9, line 34 through page 10, line 2 of the accompanying description in the specification as originally filed.

Claims 20-26 are left unchanged.

New claims 27-32 are added to recite additional features. It is respectfully submitted that no new matter is added, since support for the new claims may be found, for example, at least in Figs. 11 through 37, and 59 through 74 of the pending application and, for example, at least on page 9, line 34 through page 10, line 2, page 12, lines 4-11, and page 13, lines 5-11 of the accompanying description in the specification as originally filed.

Entry of the LIST OF CURRENT CLAIMS is respectfully requested in the next Office communication.

2. Rejection of claims 19-26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent no. 6,290,684 (*Herrick*) in view of U.S. patent no. 5,171,270 (*Herrick*) and in view of U.S. publication no. 2004/0092857 (*Clayman et al.*)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to amended claim 19, from which claims 20-26 depend.

By way of review, amended claim 19 requires a punctal plug having a shaft, a tip portion, a brim, and a fine thread removably inserted into a part of the punctal plug. The fine thread is used in two manners, the first is if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, the second is if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread.

Thus, if the plug is not properly positioned, for example, if the plug is accidentally inserted too deeply into a canaliculus, then the plug can be pulled out by pulling both ends of the fine thread so as to remove the plug from the improper position.

However, if the plug is properly positioned, then the fine thread is removed from the plug, while the plug remains in place in the proper position. This is accomplished by pulling on one end of the thread, such that the thread is removed from the punctal plug, while the plug remains in position. In other words, the plug itself is not removed, but instead, is maintained in the proper position, while the thread is removed from the plug. If it is desired to remove the punctal plug after the thread has been removed from the plug, the plug can be removed by grasping the brim of the plug with a pair of tweezers, for example. It may be desired to remove the plug in this manner if some problem, like epiphora, takes place.

It is respectfully submitted that the proposed combination of the *Herrick* '684, and the *Herrick* '270 patents, and the *Clayman* publication fails to disclose at least a fine thread used in two manners, first if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, second if

the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread, as is required by amended claim 19.

The *Herrick* '684 patent discloses a punctum plug 178 having an elongated member 180 having a central axis and a pair of spaced ends 184 and 186 (col. 12, lines 9-13).

As acknowledged in the Office action on page 2, the *Herrick* '684 patent fails to disclose a fine thread.

The Office action next turns to the *Herrick* '270 patent, which discloses a canalicular implant 20 having an elongated central member 22 with a pair of ends 26, 34 (col. 6, lines 55-61). One of the ends is a collapsible flared end 36 having an outer ring 40 (col. 6, lines 60-61; col. 7, lines 1-4).

An elongated, thread-like member 44, a cord or a long slender flexible material, can be attached to the outer ring 40 of the collapsible flared section 36 and be of sufficient length to extend from the canalicular implant, located within the horizontal portion of the canaliculus, to the punctum such that an eye surgeon can apply a pulling force on the thread-like member to retrograde and remove the canalicular implant (col. 5, lines 11-20; col. 7, lines 19-36).

In other words, the thread-like member 44 has a single end which is pulled by an eye surgeon in order to remove the canalicular implant, which is in direct contrast to amended claim 19, which requires that the fine thread is removed from the punctal plug by pulling one end of the thread.

Further, the *Herrick* '270 patent fails to disclose or suggest that the thread-like member 44 is removable from the canalicular implant.

After the canalicular implant 20 of the *Herrick* '270 patent is properly positioned in the horizontal portion of the canaliculus, if the thread-like member is too long, then a part of the thread-like member, which extends over the punctum, should be cut so as to avoid irritation of the patient's eye. Thus, in a usual case, the thread-like member is arranged in such a way that the thread-like member does not extend out of the punctum. For this reason, it is difficult to pull out and remove the

canalicular implant after it is properly positioned, even if such a short-cut thread-like member is attached to the canalicular implant. Further, the upper end of the thread-like member may move deeply so as to move far from the punctum, which can sometimes result in epiphora. In such a case, dacryocystorhinostomy or the like may be required.

Turning to the *Clayman* publication, a ureteral stent for assisting movement of urine along a patient's ureter and into the patient's bladder is disclosed. As is discussed in detail, an extraction thread is used to remove the stent (paragraphs [0013], [0014], [0049], [0050], [0055]). There is no disclosure that the extraction thread is removed from the stent once the stent has been properly positioned, and further, a person having ordinary skill in the art would not have removed the extraction thread from the stent since the use of the extraction thread prevents the need for cystoendoscopy to remove the stent (paragraph [0049]).

Thus, it is respectfully submitted that the proposed combination of the *Herrick* '684, and the *Herrick* '270 patents, and the *Clayman* publication fails to disclose at least a fine thread used in two manners, first if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, second if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread, as is required by amended claim 19, since none of the *Herrick* '684, and the *Herrick* '270 patents, and the *Clayman* publication discloses at least the second manner recited in amended claim 19.

Accordingly, a *prima facie* case of obviousness cannot be established with respect to amended claim 19, and withdrawal of this rejection is respectfully requested.

As mentioned above, applicant submits that independent claim 19 is patentable and therefore, claims 20-26, which depend from claim 19, are also considered to be patentable as containing all of the elements of claim 19, as well as for their respective recited features.

3. New claims

New claims 27-32 are considered to be patentable by way of the same reasoning as discussed above. Namely, independent claim 27, from which claims 28-32 depend, recites a punctal plug comprising a shaft, a tip portion, and a brim, and a fine thread for removable insertion into one of the shaft, the tip portion, the brim, or into the shaft and the tip portion, or into the shaft and the brim, wherein two ends of the fine thread can be pulled to pull the punctal plug from the canaliculus and one end of the thread can be pulled to remove the thread from the punctal plug.

As discussed in detail above with respect to amended claim 19, the cited prior art fails to disclose or suggest this configuration. Accordingly, new claim 27 is considered to be patentable. Therefore, claims new claims 28-32, which depend from claim 27, are also considered to be patentable as containing all of the elements of claim 27, as well as for their respective recited features.

4. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

Please charge any additional fees required or credit any overpayments in connection with this paper to Deposit Account No. 02-0200.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicant's attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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